

**AMENDMENTS TO THE CLAIMS**

Please amend the claims as follows.

5        Claim 1 (withdrawn): A pharmaceutical formulation comprising one or  
more excipients and 3 $\alpha$ ,16 $\alpha$ ,17 $\beta$ -trihydroxy-5 $\alpha$ -androstane, 3 $\alpha$ ,16 $\alpha$ -  
dihydroxy-17-oxo-5 $\alpha$ -androstane, 3 $\beta$ ,16 $\alpha$ ,17 $\beta$ -trihydroxy-5 $\alpha$ -androstane,  
3 $\beta$ ,16 $\alpha$ -dihydroxy-17-oxo-5 $\alpha$ -androstane, 3 $\alpha$ ,16 $\beta$ ,17 $\beta$ -trihydroxy-5 $\alpha$ -  
androstane, 3 $\alpha$ ,16 $\beta$ -dihydroxy-17-oxo-5 $\alpha$ -androstane, 3 $\beta$ ,16 $\beta$ -dihydroxy-17-  
oxo-5 $\alpha$ -androstane, 3 $\alpha$ ,16 $\alpha$ ,17 $\beta$ -trihydroxy-5 $\beta$ -androstane, 3 $\alpha$ ,16 $\alpha$ -dihydroxy-  
10    17-oxo-5 $\beta$ -androstane, 3 $\beta$ ,16 $\alpha$ ,17 $\beta$ -trihydroxy-5 $\beta$ -androstane, 3 $\beta$ ,16 $\alpha$ -  
dihydroxy-17-oxo-5 $\beta$ -androstane, 3 $\alpha$ ,16 $\beta$ ,17 $\beta$ -trihydroxy-5 $\beta$ -androstane,  
3 $\alpha$ ,16 $\beta$ -dihydroxy-17-oxo-5 $\beta$ -androstane, 3 $\beta$ ,16 $\beta$ -dihydroxy-17-oxo-5 $\beta$ -  
androstane or a 2-oxa, 11-oxa or 19-nor analog of any of these compounds.

15        Claim 2 (withdrawn): The pharmaceutical formulation of claim 1  
wherein the compound is 3 $\alpha$ ,16 $\alpha$ ,17 $\beta$ -trihydroxy-5 $\alpha$ -androstane.

20        Claim 3 (withdrawn): The pharmaceutical formulation of claim 1  
wherein the compound is 3 $\alpha$ ,16 $\alpha$ -dihydroxy-17-oxo-5 $\alpha$ -androstane.

25        Claim 4 (withdrawn): A pharmaceutical formulation for buccal or  
sublingual administration comprising one or more excipients and a compound  
wherein the compound is 16 $\alpha$ -fluoro-17-oxoandrost-5-ene, 3 $\alpha$ -hydroxy-16 $\alpha$ -  
fluoro-17-oxoandrost-5-ene, 3 $\beta$ -hydroxy-16 $\alpha$ -fluoro-17-oxoandrost-5-ene 7 $\alpha$ -  
hydroxy-16 $\alpha$ -fluoro-17-oxoandrost-5-ene, 7 $\beta$ -hydroxy-16 $\alpha$ -fluoro-17-  
oxoandrost-5-ene, 16 $\alpha$ -fluoro-7,17-dioxoandrost-5-ene.

30        Claim 5 (withdrawn): The pharmaceutical formulation of claim 4  
wherein the compound is micronized.

Claim 6 (withdrawn): The pharmaceutical formulation of claim 4  
wherein the compound is 16 $\alpha$ -fluoro-17-oxoandrost-5-ene.

5 Claim 7 (withdrawn): A pharmaceutical formulation comprising one or  
more excipients and two or more of 3 $\beta$ -hydroxy-16 $\alpha$ -bromo-17-oxo-5 $\alpha$ -  
androstane, 3 $\beta$ -hydroxy-16 $\beta$ -bromo-17-oxo-5 $\alpha$ -androstane and 3 $\beta$ -hydroxy-  
16 $\alpha$ -bromo-17-oxo-5 $\alpha$ -androstane hemihydrate.

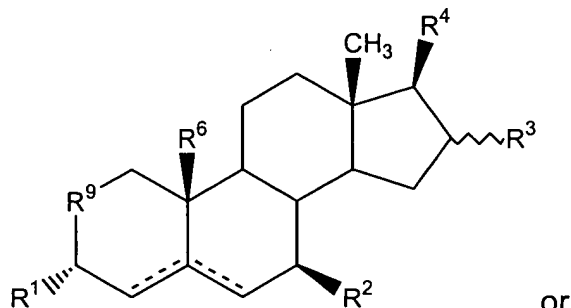
10 Claim 8 (withdrawn): The pharmaceutical formulation of claim 7  
wherein the pharmaceutical formulation is for oral, buccal, sublingual or  
aerosol administration.

15 Claim 9 (original): The pharmaceutical formulation of claim 7  
comprising 7 3 $\beta$ -hydroxy-16 $\beta$ -bromo-17-oxo-5 $\alpha$ -androstane and 3 $\beta$ -hydroxy-  
16 $\alpha$ -bromo-17-oxo-5 $\alpha$ -androstane hemihydrate.

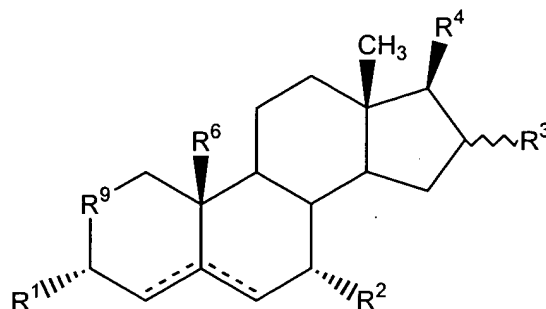
20 Claim 10 (withdrawn): The pharmaceutical formulation of claim 9  
wherein the pharmaceutical formulation is for oral, buccal, sublingual or  
aerosol administration.

Claims 11-31 (canceled)

25 Claim 32 (new): A method to treat osteoporosis or a bone fracture in a  
subject in need thereof, comprising administering to the subject an effective  
amount of a compound having the structure



or



wherein,

R<sup>1</sup> is -OR<sup>PR</sup>, -SR<sup>PR</sup>, -N(R<sup>PR</sup>)<sub>2</sub>, -N<sub>3</sub>, -NO<sub>2</sub>, an ester, a thioester, a phosphoester, a phosphothioester, a sulfate ester, an amino acid, a peptide,  
5 an ether, a thioether, a carbonate, a carbamate, an optionally substituted monosaccharide or an optionally substituted oligosaccharide;

R<sup>2</sup> and R<sup>3</sup> independently are -H, -OR<sup>PR</sup>, =O, -SR<sup>PR</sup>, =S, -N(R<sup>PR</sup>)<sub>2</sub>, -N<sub>3</sub>, =NOH, -CN, -NO<sub>2</sub>, an amino acid, a peptide, an ether, a thioether, an acyl group, a thioacyl group, a carbonate, a carbamate, a thioacetal, a halogen, a  
10 substituted alkyl group, an optionally substituted alkenyl group, an optionally substituted alkynyl group;

R<sup>4</sup> is -OR<sup>PR</sup>, =O, -SR<sup>PR</sup>, =S, -N(R<sup>PR</sup>)<sub>2</sub>, -N<sub>3</sub>, =NOH, -NO<sub>2</sub>, an ester, a thioester, a phosphoester, a phosphothioester, a phosphonoester, a phosphiniester, a sulfate ester, an amino acid, a peptide, an ether, a  
15 thioether, an optionally substituted heteroaryl moiety, an optionally substituted monosaccharide or an optionally substituted oligosaccharide;

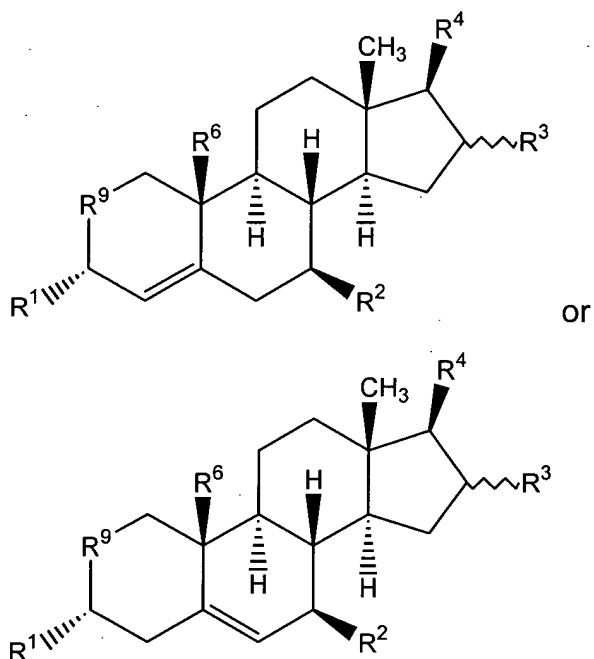
R<sup>6</sup> is -H or optionally substituted alkyl;

R<sup>9</sup> is -CHR<sup>10</sup>-, wherein R<sup>10</sup> is -H, -OH, =O, -SH, halogen, an ester, a thioester, an amino acid, a peptide, an ether, a thioether, optionally  
20 substituted alkyl, optionally substituted alkenyl or optionally substituted alkynyl;

R<sup>13</sup> independently is C<sub>1-6</sub> alkyl;

R<sup>PR</sup> independently are -H or a protecting group.

25 Claim 33 (new): The method of claim 32 wherein the subject has osteoporosis and the compound has the structure



Claim 34 (new): The method of claim 33 wherein

- (1)  $R^1$  and  $R^4$  are -OH,  $R^2$  and  $R^3$  are -H and  $R^9$  is -CH<sub>2</sub>-;
- (2)  $R^1$  and  $R^4$  are -OH,  $R^2$  is -H,  $R^3$  is -Br and  $R^9$  is -CH<sub>2</sub>-;
- (3)  $R^1$  and  $R^4$  are -OH,  $R^2$  is -H,  $R^3$  is -F and  $R^9$  is -CH<sub>2</sub>-;
- (4)  $R^1$ ,  $R^2$  and  $R^4$  are -OH,  $R^3$  is -H and  $R^9$  is -CH<sub>2</sub>-;
- (5)  $R^1$ ,  $R^2$  and  $R^4$  are -OH,  $R^3$  is -Br and  $R^9$  is -CH<sub>2</sub>-;
- (6)  $R^1$ ,  $R^2$  and  $R^4$  are -OH,  $R^3$  is -F and  $R^9$  is -CH<sub>2</sub>-;
- (7)  $R^1$ ,  $R^3$  and  $R^4$  are -OH,  $R^2$  is -H and  $R^9$  is -CH<sub>2</sub>-;
- (8)  $R^1$ ,  $R^2$ ,  $R^3$  and  $R^4$  are -OH and  $R^9$  is -CH<sub>2</sub>-;

(9)  $R^1$  and  $R^4$  independently are -OR<sup>PR</sup>, -SR<sup>PR</sup>, -N(R<sup>PR</sup>)<sub>2</sub>, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate,  $R^2$  and  $R^3$  are -H and  $R^9$  is -CH<sub>2</sub>-;

(10)  $R^1$  and  $R^4$  independently are -OR<sup>PR</sup>, -SR<sup>PR</sup>, -N(R<sup>PR</sup>)<sub>2</sub>, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate,  $R^2$  is -H,  $R^3$  is -Br and  $R^9$  is -CH<sub>2</sub>-;

(11)  $R^1$  and  $R^4$  independently are -OR<sup>PR</sup>, -SR<sup>PR</sup>, -N(R<sup>PR</sup>)<sub>2</sub>, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate,  $R^2$  is -H,  $R^3$  is -F and  $R^9$  is -CH<sub>2</sub>-;

(12)  $R^1$  and  $R^4$  independently are  $-OR^{PR}$ ,  $-SR^{PR}$ ,  $-N(R^{PR})_2$ , an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate,  $R^2$  is  $-H$ ,  $R^3$  is  $-OH$  and  $R^9$  is  $-CH_2-$ ;

(13)  $R^1$  and  $R^4$  independently are  $-OR^{PR}$ ,  $-SR^{PR}$ ,  $-N(R^{PR})_2$ , an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate,  $R^2$  and  $R^3$  are  $-OH$  and  $R^9$  is  $-CH_2-$ ;

(14)  $R^1$  and  $R^4$  independently are  $-OR^{PR}$ ,  $-SR^{PR}$ ,  $-N(R^{PR})_2$ , an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate,  $R^2$  is  $-OH$ ,  $R^3$  is  $-H$ ,  $-F$ ,  $-Cl$  or  $-Br$  and  $R^9$  is  $-CH_2-$ ;

(15)  $R^1$  is  $-H$ ,  $R^2$  is  $-OH$  or  $=O$ ,  $R^3$  is  $-OH$ ,  $-F$ ,  $-Cl$  or  $-Br$ ,  $R^4$  is  $-OR^{PR}$ ,  $-SR^{PR}$ ,  $-N(R^{PR})_2$ , an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate and  $R^9$  is  $-CH_2-$ ;

(16)  $R^1$  and  $R^2$  are  $-H$ ,  $R^3$  is  $-OH$  or  $=O$ ,  $-F$ ,  $-Cl$  or  $-Br$ ,  $R^4$  is  $-OR^{PR}$ ,  $-SR^{PR}$ ,  $-N(R^{PR})_2$ , an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate and  $R^9$  is  $-CH_2-$ ;

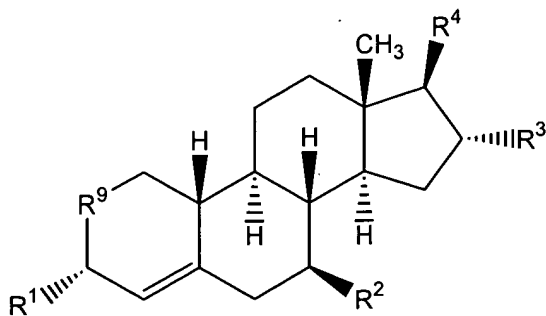
(17)  $R^1$  is  $-OH$ ,  $R^2$  is  $-OH$  or  $=O$ ,  $R^3$  is  $-H$ ,  $R^4$  is  $-OR^{PR}$ ,  $-SR^{PR}$ ,  $-N(R^{PR})_2$ , an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate and  $R^9$  is  $-CH_2-$ ;

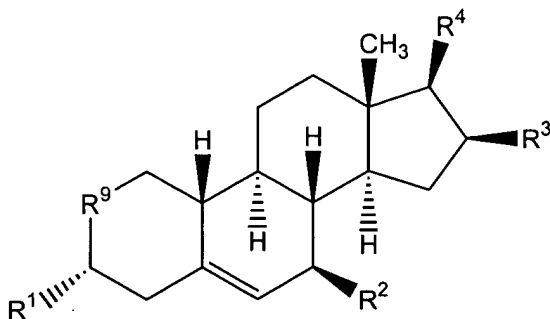
(18) any of (1) through (17) above wherein  $R^9$  is  $-O-$  instead of  $-CH_2-$ ;

or

(19) any of (1) through (17) above wherein  $R^9$  is  $-NH-$  instead of  $-CH_2-$ .

Claim 35 (new): The method of claim 32 wherein the compound has the structure





Claim 36 (new): The method of claim 35 wherein the subject has osteoporosis and the compound is 3 $\alpha$ ,17 $\beta$ -dihydroxy-19-norandrost-4-ene,  
5 3 $\alpha$ ,17 $\beta$ -dihydroxy-19-norandrost-5-ene, 3 $\alpha$ ,17 $\beta$ -dihydroxyandrost-4-ene, 3 $\alpha$ ,17 $\beta$ -dihydroxyandrost-5-ene, 3 $\alpha$ ,16 $\alpha$ ,17 $\beta$ -trihydroxy-19-norandrost-4-ene, 3 $\alpha$ ,16 $\alpha$ ,17 $\beta$ -trihydroxy-19-norandrost-5-ene, 3 $\alpha$ ,16 $\alpha$ ,17 $\beta$ -trihydroxyandrost-4-ene, 3 $\alpha$ ,16 $\alpha$ ,17 $\beta$ -trihydroxyandrost-5-ene, 3 $\alpha$ ,7 $\beta$ ,17 $\beta$ -trihydroxy-19-norandrost-4-ene, 3 $\alpha$ ,7 $\beta$ ,17 $\beta$ -trihydroxy-19-norandrost-5-ene, 3 $\alpha$ ,7 $\beta$ ,17 $\beta$ -trihydroxyandrost-4-ene,  
10 ene, 3 $\alpha$ ,7 $\beta$ ,17 $\beta$ -trihydroxyandrost-5-ene, 3 $\alpha$ ,17 $\beta$ -dihydroxy-16 $\alpha$ -fluoro-19-norandrost-4-ene, 3 $\alpha$ ,17 $\beta$ -dihydroxy-16 $\alpha$ -fluoro-19-norandrost-5-ene, 3 $\alpha$ ,17 $\beta$ -dihydroxy-16 $\alpha$ -fluoroandrost-4-ene, 3 $\alpha$ ,17 $\beta$ -dihydroxy-16 $\alpha$ -fluoroandrost-5-ene, 3 $\alpha$ ,17 $\beta$ -dihydroxy-16 $\alpha$ -bromo-19-norandrost-4-ene, 3 $\alpha$ ,17 $\beta$ -dihydroxy-16 $\alpha$ -bromo-19-norandrost-5-ene, 3 $\alpha$ ,17 $\beta$ -dihydroxy-16 $\alpha$ -bromoandrost-4-ene or  
15 3 $\alpha$ ,17 $\beta$ -dihydroxy-16 $\alpha$ -bromoandrost-5-ene.

Claim 37 (new): The method of claim 36 wherein the compound is 3 $\alpha$ ,17 $\beta$ -dihydroxy-19-norandrost-4-ene.